

REMARKS

Requirement for Restriction/Election of Species

The Office Action alleges that the pending claims define unrelated inventions, and requires restriction of the invention to one of the following groups of claims:

- (I) claims 1-11 and 36-39, drawn to a method of administering to a mammal or a tumor cell a polypeptide of SEQ ID NO: 1 or 2 (class 514, subclass 2),
- (II) claims 12-19, drawn to a method of administering to a mammal an antagonist of β_1 integrin to inhibit metastasis of a tumor cell (class 514, subclass 2),
- (III) claims 20-27, drawn to a method of administering to a mammal an antagonist of CXCL12 to inhibit metastasis of a tumor cell (class 514, subclass 2), and
- (IV) claims 28-35, drawn to a method of administering to a mammal an antagonist of α_4 integrin to inhibit metastasis of a tumor cell (class 514, subclass 2).

The Office Action also alleges that certain claims are directed to patentably distinct species, and requires election of a single species for prosecution. In particular, the Office Action indicates that the following compounds are patentably distinct from each other by virtue of their structure: SEQ ID NO: 1 (claim 1), SEQ ID NO: 2 (claim 2), antagonist of CRCR4 (claim 11), antagonist of β_1 integrin (claim 12), antagonist of CXCL12 (claim 20), and antagonist of α_4 integrin (claim 28). The Office Action requests that the Applicants elect one species of polypeptide or one species of antagonist for prosecution, depending upon the claim election.

Applicants' Election of Claims/Species in Compliance with 37 C.F.R § 1.141

Applicants elect, with traverse, the claims of group I directed to a method of inhibiting metastasis of a tumor cell in a mammal comprising administering a polypeptide of SEQ ID NO:1. However, Applicants note that claim 11, unlike the other claims of group I, is directed to a method involving the use of an antagonist of CXCR4. Thus, it does not appear that group I should include claim 11.

Applicants also elect, with traverse, the species of polypeptide defined by SEQ ID NO:2. Claims 2 and 37 read upon the elected species. Upon allowance of the generic claim, Applicants understand that the Patent Office will consider the other claimed polypeptides.

Reconsideration of the requirements for restriction and election of species is respectfully requested for the reasons discussed below.

Discussion of the Restriction Requirement

There are two separate criteria for a proper requirement for restriction between patentably distinct inventions: (i) the inventions must be independent or distinct as claimed, *and* (ii) there must be a serious burden on the Examiner if restriction is not required. Both of these criteria must exist for a restriction requirement to be proper, and “[i]f the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to distinct or independent inventions” (M.P.E.P. § 803, emphasis added). Allegations that a claimed invention satisfies these criteria must be supported by reasoning and/or examples.

In the case at hand, the Office Action fails to meet the above-criteria. The Office Action alleges that the groups of claims set forth therein have acquired a “separate status” in the art. However, the Office Action provides no evidence in support of this conclusion. Indeed, all of the subject matter of the pending claims has been classified in the same class and subclass. Furthermore, the Office Action does not even allege that there would be any serious burden on the Examiner in the absence of the restriction requirement. Inasmuch as the subject matter of the pending claims is searchable in the same class and subclass, there does not appear to be any “serious burden” on the Examiner that would warrant the restriction requirement. Thus, the Patent Office has failed to meet the criterion for a proper restriction requirement, and the restriction requirement should be withdrawn.

Discussion of the Requirement for Election of Species

As with the restriction requirement, the Office Action’s requirement for election of species is not well founded. As the Applicants have elected the claims of Group I, the requirement for election of species is addressed below with respect to the claims of Group I. However, the following comments with respect to the Group I claims are equally applicable to the other groups of claims, and in the event the restriction requirement is withdrawn, the requirement for species election should be withdrawn as to all claims for the same reasons.

An election of species is proper under 37 C.F.R. § 1.146 only in an application containing (a) a claim to a generic invention and claims to more than one patentably distinct species embraced by the claimed genus, or (b) a claim directed to an unreasonable number of species. 37 C.F.R. § 1.146. The Office Action does not allege that any claim of the present application is directed to an unreasonable number of species, nor does the Office Action identify more than one patentably distinct species recited in the claims of Group I. Contrary to the Office Action’s assertions, SEQ ID NO:1 and SEQ ID NO:2 do not define different

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species of polypeptides. Rather, SEQ ID NO:1 defines a *genus* of polypeptides that encompasses the polypeptide defined by SEQ ID NO:2. Accordingly, the Office Action has not set forth any proper basis for the requirement for the election of a species, and such requirement should be withdrawn.

Conclusion

The application is considered in good and proper form for allowance, and the Examiner is respectfully requested to pass this application to issue. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "John L. Gase", is written over a horizontal line. The signature is fluid and cursive, with a long horizontal stroke extending to the left.

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